

**IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF NEW JERSEY**

CORCEPT THERAPEUTICS, INC.,

Plaintiff,

v.

TEVA PHARMACEUTICALS USA, INC.,

Defendant.

C.A. No. 18-03632 (RMB)(LDW)  
(consolidated)

**DEFENDANT'S NOTICE PURSUANT TO 35 U.S.C. § 282**

Pursuant to 35 U.S.C. § 282, Defendant hereby provides notice to Plaintiff of (1) the country, number, date, and name of the patentee of any patent and (2) the title, date, and page numbers of any publication Defendant may rely upon to anticipate the asserted patents or show the state of the art. Defendant also provides the name and address of any person who may be relied upon as the prior inventor or as having prior knowledge of or as having previously used or offered for sale the invention of the patent in suit. In addition to the items expressly listed in this notice, Defendant also incorporates by reference each patent or publication listed on the face of U.S. Patent Nos. 10,195,214, 10,500,216, 10,842,800, and 10,842,801 and all information set forth in the invalidity contentions, written discovery responses, and expert reports submitted by Defendant in this matter and the asserted patents' file histories.

The identification of a particular patent or publication is not an admission or representation that reliance upon such patent or publication is necessary to establish any of Defendant's defenses or counterclaims.

**I. Patents and Publications:****PATENTS**

<b><u>Country</u></b>	<b><u>Number</u></b>	<b><u>Issue Date</u></b>	<b><u>Name of Patentee</u></b>
USA	10,195,214	02/05/2019	Joseph K. Belanoff
USA	10,500,216	12/10/2019	Joe Belanoff; Robert Roe; Caroline Loewy
USA	10,842,800	11/24/2020	Joseph K. Belanoff
USA	10,842,801	11/24/2020	Joe Belanoff; Robert Roe; Caroline Loewy
USA	File History of U.S. Patent No. 10,500,216	03/12/2020	

**PUBLICATIONS**

<b><u>Title</u></b>	<b><u>Publication Date</u></b>	<b><u>Page Nos.</u></b>
Aanderud, S. and Myking, O., “Plasma Cortisol Concentrations after Oral Substitution of Cortisone in the Fasting and Non-Fasting State,” <i>Acta Med Scand.</i> , 210(3):157–61 (1981)	1981	157–161
Bagchus, W. et al., “Important Effect of Food on the Bioavailability of Oral Testosterone Undecanoate,” <i>Pharmacotherapy</i> , 23(3):319–25 (2003)	03/2003	319–325
Belanoff, J. et al., “An Open Label Trial of C-1073 (Mifepristone) for Psychotic Major Depression*,” <i>Biol Psychiatry</i> , 52(5):386–92 (2002)	04/17/2002	386–392
Berthois, Y. et al., “A multiparametric analysis of endometrial estrogen and progesterone receptors after the postovulatory administration of mifepristone*†,” <i>Fertility and Sterility</i> , 55(3):547–54 (1991)	03/1991	547–554
Brogden, R. et al., “Mifepristone, A Review of its Pharmacodynamic and Pharmacokinetic Properties, and Therapeutic Potential,” <i>Drugs</i> , 45(3):384–409 (1993)	03/1993	384–409
Castinetti, F. et al., “Merits and pitfalls of mifepristone in Cushing's syndrome,” <i>Eur J Endocrinol.</i> , 160(6):1003–10 (2009)	06/2009	1003–1010
Castinetti, F. et al., “Medical Treatment of Cushing's Syndrome: Glucocorticoid Receptor Antagonists and Mifepristone,” <i>Neuroendocrinology</i> , 92(suppl 1):125–30 (2010)	09/10/2010	125–130
Chu, J. et al., “Successful Long-Term Treatment of Refractory Cushing’s Disease with High-Dose Mifepristone (RU486),” <i>J Clin Endocrinol Metab.</i> , 86(8):3568–73 (2001)	08/2001	3568–3573

<b><u>Title</u></b>	<b><u>Publication Date</u></b>	<b><u>Page Nos.</u></b>
Davis, J. et al., “Guidelines for Counselling Patients Receiving Drugs Used in the Treatment of Neoplastic Disease: a Pharmacist’s Guide to Advisory Labels and Patient Information,” <i>Austl J Hosp Pharm.</i> , 31(1):51–5 (2001)	2001	51–55
de Lignières, B., “Oral Micronized Progesterone,” <i>Clin Ther.</i> , 21(1):41–60 (1999)	01/1999	41–60
Food & Drug Administration, Guidance for Industry, Food-Effect Bioavailability and Fed Bioequivalence Studies (2002)	12/2002	
Form 10-K, Corcept Therapeutics Incorporated (03/26/2010)	03/26/2010	
Heikinheimo, O., “Clinical Pharmacokinetics of Mifepristone,” <i>Clin Pharmacokinet.</i> , 33(1):7–17 (1997)	07/1997	7–17
Heikinheimo, O. et al., “The pharmacokinetics of mifepristone in humans reveal insights into differential mechanisms of antiprogesterone action,” <i>Contraception</i> , 68(6):421–26 (2003)	03/17/2003	421–426
Johanssen, S. and Allolio, B., “Mifepristone (RU 486) in Cushing’s syndrome,” <i>Eur J Endocrinol.</i> , 157(5):561–69 (2007)	11/2007	561–569
Lindberg, C., “Emergency Contraception: The Nurse’s Role in Providing Postcoital Options,” <i>J Obstet Gynecol Neonatal Nurs.</i> , 26(2):146–52 (1997)	04/1997	146–152
McLachlan, A. and Ramzan, I., “Meals and medicines,” <i>Australian Prescriber</i> , 29(2):40–42 (2006)	04/01/2006	40–42

<b><u>Title</u></b>	<b><u>Publication Date</u></b>	<b><u>Page Nos.</u></b>
Nieman, L. et al., “Successful Treatment of Cushing’s Syndrome with the Glucocorticoid Antagonist RU 486*,” <i>J Clin Endocrinol Metab.</i> , 61(3):536–40 (1985)	09/1985	536–540
Para, M. et al., “Phase I/III Trial of the Anti-HIV Activity of Mifepristone in HIV-Infected Subjects ACTG 5200,” <i>J Acquir Immune Defic Syndr.</i> , 53(4):491–495 (2010)	04/01/2010	491–495
Porter, C. et al., “Lipids and lipid-based formulations: optimizing the oral delivery of lipophilic drugs,” <i>Nature Reviews Drug Discovery</i> , 6:231–48 (2007)	03/2007	231–248
Sääv, I. et al., “Medical abortion in lactating women – low levels of mifepristone in breast milk,” <i>Acta Obstet Gynecol Scand.</i> , 89(5):618–22 (2010)	05/2010	618–622
Sarkar, N., “Mifepristone: bioavailability, pharmacokinetics and use-effectiveness,” <i>Eur J Obstet Gynecol Reprod Biol.</i> , 101(2):113–20 (2002)	03/10/2002	113–120
Sartor, O. and Cutler, G., “Mifepristone: Treatment of Cushing’s Syndrome,” <i>Clin Obstet Gynecol.</i> , 39(2):506–10 (1996)	06/1996	506–510

## II. Persons with Knowledge:

- a. The inventors identified in U.S. Patent Nos. 10,195,214, 10,500,216, 10,824,800, and 10,824,801. The names and addresses of those inventors are provided therein and in the associated file histories.
- b. Any one or more of the inventors of the patents identified in Section I above. Those inventors' names and addresses are identified in the respective patents and in the associated file histories.
- c. Any one or more of the authors of the publications identified in Section I above. Those authors' names and addresses are identified in the respective publications.

August 11, 2023

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